STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

v **File No. 122641-001**

Blue Cross Blue Shield of Michigan

Respondent

_____

Issued and entered
this _22nd___ day of December 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On August 1, 2011, XXXXX, authorized representative of XXXXX (Petitioner), filed with the Commissioner of Financial and Insurance Regulation a request for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. The Commissioner reviewed the request and accepted it on August 8, 2011.

The Commissioner notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information it used to make its adverse determination. The Commissioner received BCBSM's response on August 19, 2011.

Because the case involves medical issues, the Commissioner assigned the case to an independent medical review organization. The reviewer's analysis and recommendations were submitted to the Commissioner on August 22, 2011.

II. FACTUAL BACKGROUND

The Petitioner receives group health care benefits through a plan underwritten by BCBSM. Her benefits are defined in BCBSM's *Simply Blue Group Benefit Certificate* (the certificate).

The Petitioner has Wolff-Parkinson-White syndrome[1] and a history of tachycardia and near syncope.[2] Her physician prescribed mobile cardiac outpatient telemetry (MCOT) services from March16 to April 14, 2011. MCOT is a system that captures and transmits cardiac arrhythmia information as it occurs. The charge for the MCOT services is $4,500.00.

BCBSM denied coverage, concluding that the procedure is investigational and therefore not a benefit under the certificate.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM held a managerial-level conference and issued a final adverse determination dated June 16, 2011, affirming its position.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's MCOT services?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's authorized representative wrote in the request for external review:

> . . . Contrary to the finding in the Plan Denial Letter, and the denial of the first appeal the [MCOT] Services are well-established as clinically effective and are a covered Plan benefit that were medically necessary and appropriate for this Patient. This conclusion is supported by the clinical determinations of the Ordering Physician, the standards of care in the medical community, studies in peer-reviewed and other medical literature, the terms of the Patient's Plan coverage and applicable law.
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> . . . This technology was approved by the FDA in November 1998 and is covered by the Level 1CPT codes 93229 for the technical component and 93228 for the professional component. Mobile cardiovascular telemetry services for the indication involved in this case have now been used effectively by the medical community in the United States for over a decade, and the health plans that cover this clinically valuable service for this indication include, among others, Medicare . . . Tricare, Highmark BC/BS, Independence BC/BS, Wellmark BCBS, Aetna, Cigna, and Humana.

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1 Wolff-Parkinson-White syndrome is the presence of an extra, abnormal electrical pathway in the heart that leads to periods of a very fast heartbeat (tachycardia).

2 Syncope, a medical term for fainting, is the loss of consciousness resulting from insufficient blood flow to the brain.

BCBSM's Argument

BCBSM states that a service must be medically necessary in order to be a covered benefit. The certificate excludes coverage for services considered to be experimental or investigational. "Experimental treatment" is defined in the certificate (p. 7.9) as follows:

> Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

In its final adverse determination, BCBSM wrote:

> . . . The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the [outpatient cardiac monitoring] service is investigational because there have not been enough studies to prove that real-time outpatient monitoring is any better than the other currently available heart monitoring systems in improving patient health outcomes. . . .
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> * * *
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> As indicated on Page 6.3 of the [certificate], we do not pay for experimental treatment or services related to experimental treatment.

BCBSM's medical policy entitled "Real-Time Outpatient Cardiac Telemetry Monitoring" concluded:

> Real-time outpatient cardiac telemetry . . . is considered experimental/ investigational in patients who experienced symptoms suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope or syncope). While this service may be safe, its effectiveness in capturing arrhythmias for immediate treatment, as opposed to conventional outpatient cardiac monitoring has not been scientifically determined.

Commissioner's Review

The question of whether the Petitioner's cardiac telemetry monitoring was experimental or investigational for treatment of her condition was presented to an independent review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician board certified in cardiology who has been in practice for more than 18 years. The reviewer is familiar with the medical management of individuals with the Petitioner's condition. The IRO reviewer's report includes the following conclusion and analysis:

Recommended Decision:

The MAXIMUS physician consultant determined that the mobile cardiac telemetry services that the member received were investigational for diagnosis and treatment of her condition.

Rationale:

The MAXIMUS independent physician consultant, who is familiar with the medical management of patients with the member's condition, has examined the medical record and the arguments presented by the parties.

The results of the MAXIMUS physician consultant's review indicate that this case involves a 41 year-old female who has a history of Wolff-Parkinson-White syndrome and symptoms of presyncope. At issue in this appeal is whether the mobile cardiovascular telemetry services that the member received were investigational for diagnosis and treatment of her condition.

The MAXIMUS physician consultant noted that the member's symptoms of presyncope were described in a clinic note dated 3/3/11 as being associated with chest discomfort and occurring at a time related to severe cramping from her premenstrual syndrome. The MAXIMUS physician consultant also noted that an exercise stress echocardiogram performed on 3/16/11 revealed a structurally normal heart and no clear provokable ischemia. The MAXIMUS physician consultant further noted that outpatient mobile cardiac telemetry was performed from 3/16/11 to 4/14/11.

The MAXIMUS physician consultant explained that in the circumstances present in this case, if cardiac monitoring was thought to be necessary to identify potential dysrhythmias during episodes of presyncope, then non-real time (off-line) monitoring devices, such as Holter monitoring or event monitoring, would have been sufficient. The MAXIMUS physician consultant also explained that continuous off-line 24 to 48 hour Holter monitoring should be able to effectively identify symptomatic or asymptomatic dysrhythmias that occur frequently. The MAXIMUS physician consultant indicated that self-activated non-real time and non-continuous monitoring devices are effective at recording symptomatic dysrhythmias during less frequent symptoms. The MAXIMUS physician consultant also indicated that in cases of infrequent asymptomatic dysrhythmias that require identification, non-real time off-line monitoring devices with auto-triggering capability are sufficient. The MAXIMUS physician consultant explained that there was no documentation provided in the case file to show that the member was not able to effectively manage these standard monitoring devices. The MAXIMUS physician consultant also explained that there is no evidence that the member was previously evaluated by these standard monitoring devices. The MAXIMUS physician consultant indicated that current expert consensus opinions

> endorsed by several national organizations considered Holter monitoring and patient activated event recorders appropriate initial tests for evaluation of supraventricular tachycardias. [Citations omitted] The MAXIMUS physician consultant also indicated that immediate recognition and reporting of dysrhythmias through real-time mobile telemetry has not been shown to improve health outcomes compared to standard monitoring techniques.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner finds that the mobile cardiac outpatient monitor is experimental or investigational for treatment of the Petitioner's condition and is therefore not a covered benefit under the terms of the certificate.

V. ORDER

Respondent Blue Cross Blue Shield of Michigan's final adverse determination of June 16, 2011, is upheld. BCBSM is not required to cover the Petitioner's cardiac telemetry monitoring services.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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R. Kevin Clinton
Commissioner